Original Article

Differences in finished case quality between Invisalign and traditional fixed appliances: *A randomized controlled trial*

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ABSTRACT

Objectives: To compare the treatment and posttreatment effects of Invisalign aligners that incorporated SmartForce features and attachments to traditional fixed appliances.

Materials and Methods: This randomized controlled trial included 66 patients, 32 aligners, and 34 fixed-appliance patients. The median ages of the aligner and braces patients were 26.7 (interquartile range [IQR]: 9.8) and 25.9 (IQR: 16.6) years, respectively. Pretreatment occlusion was assessed using the ABO Discrepancy Index. Posttreatment (T1) and 6-month retention (T2) occlusions were quantified using the ABO Objective Grading System (OGS) scores.

Results: The braces group finished treatment significantly ($P < .001$) earlier (0.4 years) than the aligner group. The median DI scores for the aligner and braces groups were 4.5 and 7.0, respectively, which was a statistically significant ($P = .015$), but clinically insignificant, difference. There were no statistically significant between-group differences for the total OGS scores or any of the individual component scores at debond (T1) or after 6 months of retention (T2). During the posttreatment period, alignment and overjet worsened significantly in the aligner group, while buccolingual inclinations and occlusal relations improved. Over the same period, alignment worsened in the braces group and buccolingual inclinations improved. There was no statistically significant between-group difference in posttreatment changes of the total OGS scores.

Conclusions: While patients with simple malocclusions require 4.8 months longer treatment times with aligners than traditional braces, the treatment and 6-month posttreatment occlusal outcomes are similar. (*Angle Orthod.* 2022;92:173–179.)

KEY WORDS: Invisalign; Traditional fixed appliances; RCT; Human; ABO-OGS; Discrepancy index

INTRODUCTION

Orthodontics has traditionally focused on younger, growing patients.[1] However, the appliances that are currently available and patient demographics have drastically changed over time. Increasing numbers of adults are seeking treatment, and they often present with greater esthetic demands.[2] To meet their demands, an emphasis has been placed on developing appliances to treat adult patients.

The advent of clear aligner therapy is one of the most significant developments in orthodontics over the past 30 years.[2] Among the many clear aligners available, Invisalign (Align Technology, Tempe, AZ) is the most widely used.[3] Originally meant to treat mild-to-moderate cases, Invisalign has since been used to treat more complex cases, including open bites, crossbites, underbites, spacing, and even orthognathic surgery cases.[4,5]

With the increasing popularity of clear aligners, studies have been conducted to assess their limitations. It has been shown that aligners are ineffective for intruding teeth or extruding posterior teeth.[6–8] Derota-

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tion of teeth is one of the most difficult movements with clear aligners, especially for canines and premolars that are cylindrical.[1,7,9,10] Part of the problem appears to have been ClinCheck, which overestimated the amount of rotation and tooth movement that occur.[7,10,11]

Studies evaluating benefits have found that patients treated with clear aligners have better periodontal health, better hygiene, and lower oral bacterial counts than their counterparts wearing braces.[12–15] Clear aligner patients also have less severe root resorption and less discomfort than patients with braces.[16–18] Treatment duration can also be shorter with clear aligners than with braces.[16,19]

Studies comparing treatment outcomes of Invisalign and fixed appliances have been inconsistent. A comparison of non-extraction treatments showed no statistically significant between-group differences in the peer assessment rating (PAR) index or components of the PAR.[19] Another study showed that Invisalign patients had significantly higher objective grading system (OGS) scores at the end of treatment than patients treated with traditional braces.[1] Both studies evaluated differences immediately after treatment had been completed, making it impossible to determine whether settling could have occurred. The only comparison that included retention visits was a cohort study showing that alignment, as measured by the OGS, was significantly worse at the end of treatment among Invisalign than traditionally treated patients.[20] Importantly, all three studies were retrospective and none of the comparisons were based on patients treated after 2010, when Invisalign introduced SmartForce features and attachments that have been claimed to allow for more accurate and a wider range of tooth movements.

The purpose of the present study was to compare patients treated with traditional braces to patients treated with Invisalign that incorporated SmartForce features and attachments. To minimize bias, the design was prospective, the patients were randomized, and the observer was blinded.

MATERIALS AND METHODS

Data Collection

The present study was designed as a randomized controlled trial. Eighty patients were recruited from screenings at the Graduate Orthodontic Clinic of Texas A&M College of Dentistry and advertisements on the school website. To be selected for the study, patients had to meet the following criteria:

- Inclusion Criteria: Class I molar and canine relationships, non-extraction treatment, mandibular crowding of 4 mm or less, and no missing teeth (from the second molar to the second molar).
- Exclusion criteria: anterior or posterior crossbite, anterior or lateral open bite, maxillary overjet exceeding 4 mm, and impacted teeth.

Of the 80 patients, two had no final models, four had no final panoramic radiographs, five dropped out before the completion of treatment, and three had no initial cephalogram (Figure 1). The Invisalign patients were 26.7 (IQR: 9.8) years old and the braces patients were 25.9 (IQR: 16.6) years old at the start of treatment. Among the patients who completed the study, 24 were male and 42 were female. There were 32 Invisalign and 34 braces patients with complete records at the end of treatment. Of those who completed treatment, 54 returned for their 6-month retention visit, including 26 Invisalign and 28 braces patients.

Sample Allocation

Power analyses were performed using descriptive statistics previously reported for Invisalign treatment outcomes.[3,20] The analysis assumed a clinically meaningful group difference of 10 OGS points, which has been used by the American Board of Orthodontics (ABO) for distinguishing between acceptably and unacceptably treated cases. Using an alpha error of 0.05, it was estimated that 31 subjects per group were needed to achieve a power of 90%, with an effect size of 0.8. An Excel spreadsheet was used to generate the random assignment of patients to treatment groups (Invisalign or fixed appliances). The study was approved by the institutional IRB #2012-21-BCD-FB, and informed consent was obtained from all patients and parents. The study was registered at the National Institutes of Health Clinical Trials website.

Treatment Protocols

All patients were treated in the Orthodontics Department at Texas A&M College of Dentistry by an ABO-certified orthodontist. A series of custom-made clear aligners was fabricated for each patient. The patients were instructed to wear their trays 22 hours per day and to change trays every 2 weeks. Patients were evaluated at 4-week intervals. A full set of diagnostic records were taken at the first appointment. At the second appointment, an intraoral scan was taken using an iTero scanner (Align Technology, Tempe, AZ) and sent to Align Technology. The ClinCheck (Invisalign) digital models were used to fabricate a treatment plan. If correction of malocclusion was deemed to be unsatisfactory, patients were brought in for a refinement scan to fabricate additional aligners. All aligner patients had at least one refinement scan, but no one

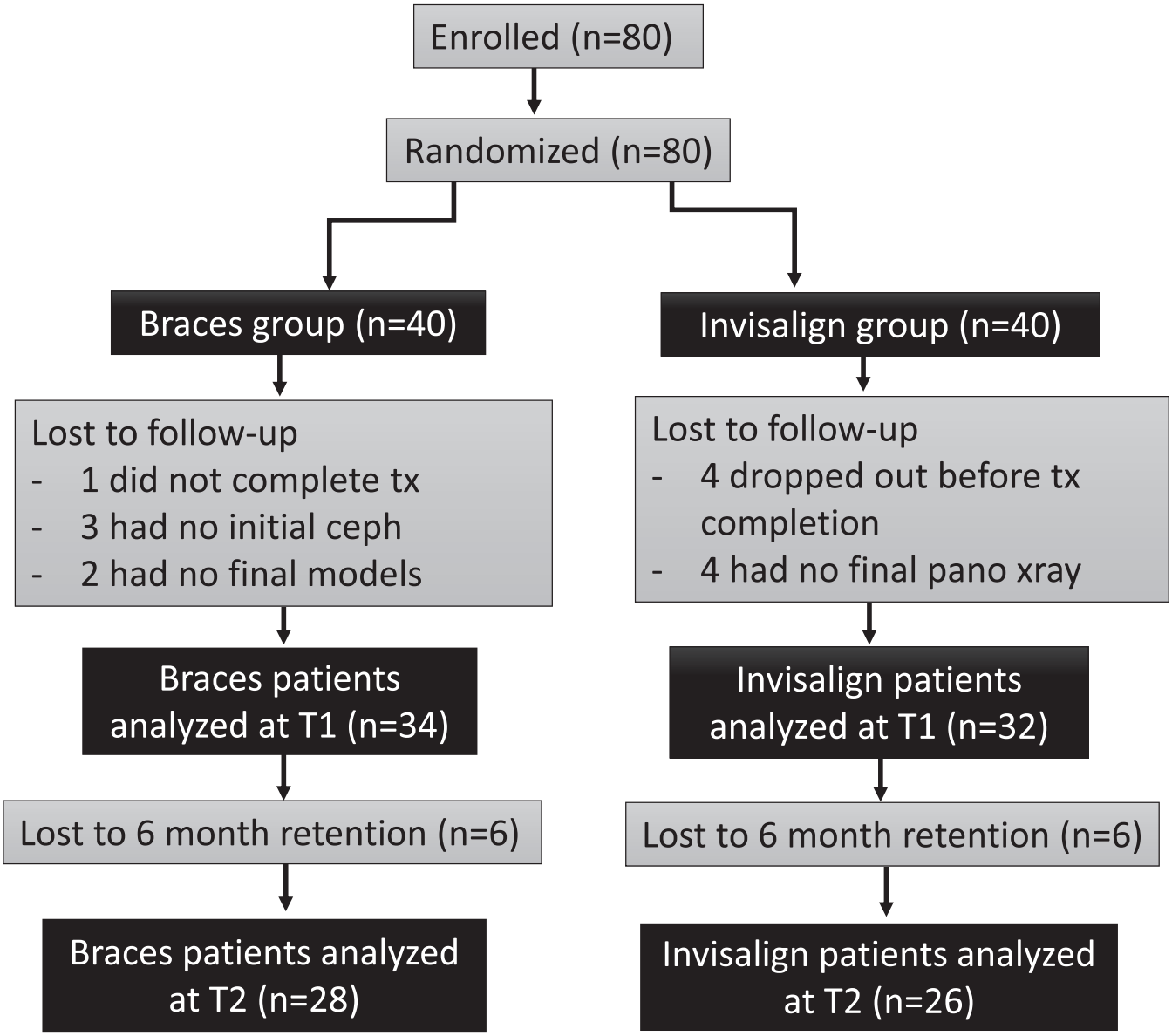

Figure 1. Flow diagram of patients enrolled in the present study.

had more than two refinement scans. Each refinement increased treatment time by approximately 4 weeks. At the debond appointment, final records were taken. One month after the completion of treatment, patients were seen for a retainer check and new photographs were taken**.** At the 6-month retention check visit, another set of records was taken.

The traditional fixed appliances consisted of 0.018 × 0.028-inch Radiance MBT (American Orthodontics, Sheboygan, WI) brackets on the upper arch and Alexander prescription brackets on the lower arch. The cases were all finished in 17×25 stainless steel wires. A combination of elastic O-rings and stainless steel ligatures was used to tie the archwires to the brackets. Fixed appliances were bonded to the maxillary and mandibular teeth at the second appointment. Adjustment appointments were scheduled every 4 weeks until the malocclusions were corrected. Once good occlusion had been achieved, brackets were debonded and final records were taken. One month after the completion of treatment, patients were seen for a retainer check and photographs**.** At the 6-month retention check visit, another set of alginate impressions and photographs was taken.

Retention

After the completion of treatment, patients were retained with upper wrap-around Hawley and lower extended Gemini retainers. If severe lower incisor

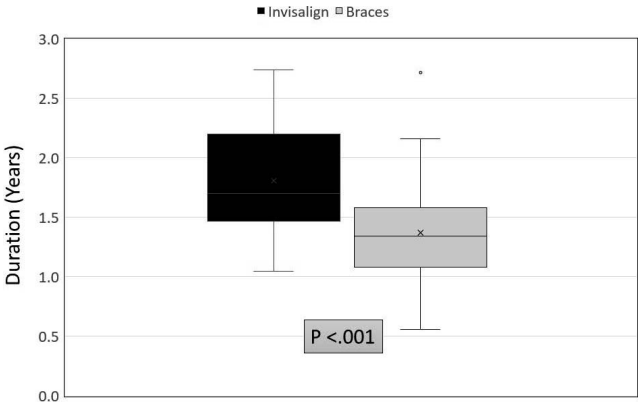

Figure 2. Box whisker plot of treatment duration.

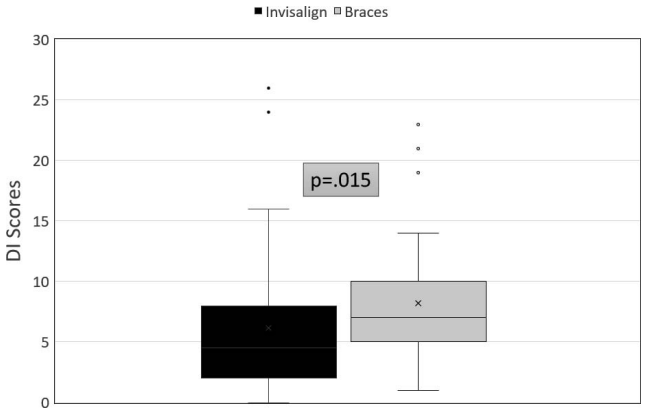

Figure 3. Box whisker plot of discrepancy index (DI) scores.

irregularity was present at pretreatment, patients were also retained with bonded lower 3-3 fixed retainers. If a diastema was present at the start of treatment, patients were retained with an additional bonded upper 2-2 fixed retainer. Thirteen patients received both a bonded lower 3-3 and an upper 2-2 fixed retainer, including 12 braces patients and 1 Invisalign patient. Thirty-seven patients received just a bonded lower 3-3 retainer: 17 braces patients, and 20 Invisalign patients. One braces patient received only an upper 2-2 fixed retainer. In total, 29 braces patients and 22 Invisalign patients received fixed retention.

Evaluations

Three time points were included in this study: T0 (initial), T1 (final), T2 (6 months retention).

Each patient's initial Discrepancy Index (DI) was assessed using the patients' T0 cephalograms and models.[21] The primary outcomes of this study were the ABO-OGS scores, including the component and overall scores at T1 and at T2.[22] The secondary outcome was the between-group differences in treatment time (T0-T1).

All cephalograms for DI calculations were digitally traced by one blinded investigator using Dolphin Imaging software. Examiner reliability was based on eight randomly selected sets of records that were scored again after 2 weeks. Reliability of over 90% was achieved.

Statistical Methods

Based on the skewness and kurtosis statistics, the variables were not normally distributed. The variables' central tendencies and dispersion were described using medians and interquartile ranges (IQR). The Mann-Whitney *U*-test was used to evaluate differences in treatment times, total ABO-OGS scores, and component scores.

RESULTS

Average treatment times from initial records to debond for the Invisalign and braces groups were 1.7 years (IQR: 0.7) and 1.3 years (IQR: 0.7), respectively (Figure 2), which was a statistically significant difference ($P < .001$). Patient ages and posttreatment duration showed no statistically significant between-group differences (Table 1).

Group Comparison

The median DI scores for the Invisalign and braces group at the start of treatment were 4.5 (IQR: 6.0) and 7.0 (IQR: 5.0), respectively (Figure 3). This difference was statistically significant ($P < .05$).

At the end of treatment (T1), the Invisalign group had better alignment, occlusal contacts, overjet, and root angulation scores, while the braces group had better marginal ridge scores (Table 2). Buccolingual inclina-

Table 1. Invisalign (INV) and Fixed Orthodontic Appliance (FOA) Patient Ages (Years) at Initial (T0), End of Treatment (T1), 6-Month Recall (T2) Appointment, as Well as the Duration Between Appointments [a]

	Aligner Group		Braces Group		Difference
Time Points (Years)	Median	IQR	Median	IQR	*P* Value
T0 Age	26.7	23.1; 32.9	25.9	23.4; 39.1	.778
T1 Age	28.6	24.7; 35.4	27.1	24.8; 40.5	.672
T2 Age	28.1	24.8; 37.7	27.6	24.8; 37.7	.849
Tx time (T0-T1)	1.7	1.5; 2.2	1.3	1.1; 1.8	<.001
Retention (T1-T2)	0.5	0.4; 0.5	0.5	0.4; 0.5	.646

[a] IQR indicates interquartile range.

Table 2. Medians and Interquartile Ranges (IQR) of OGS Scores at the End of Treatment (T1)[a]

	Aligner Group		Braces Group		Difference
OGS Component and Overall Scores	Median (50%)	IQR (25%; 75%)	Median (50%)	IQR (25%; 75%)	*P* Value
Alignment	2.0	1.0; 4.75	3.0	1.0; 4.0	.770
Marginal ridges	2.0	1.0; 2.0	1.0	0.0; 2.25	.472
Buccolingual inclination	2.0	1.0; 3.0	2.0	2.0; 4.0	.158
Occlusal contacts	1.0	0.0; 4.75	2.0	0.0; 3.25	.532
Overjet	1.0	0.0; 3.0	2.5	0.0; 6.0	.286
Interproximal contacts	0.0	0.0; 0.0	0.0	0.0; 0.0	.719
Root angulation	0.0	0.0; 1.0	1.0	0.0; 2.0	.127
Occlusal relations	2.0	0.0; 4.0	2.0	1.0; 5.25	.219
OGS	12.0	7.0; 25.0	17.0	11.75; 23.75	.158

[a] OGS indictes objective grading system.

tion, interproximal contacts, and occlusal relationships of the two groups were very similar at T1. There were no statistically significant between-group differences at T1. Overall OGS scores at the end of treatment were 12.0 (IQR: 18.0) and 17.0 (IQR: 12.0) for the Invisalign and braces groups, respectively, a difference that was not statistically significant.

At the 6-month retention visit, the Invisalign group scored better for buccolingual inclination, occlusal contacts, overjet, root angulation, and occlusal relationships, while the group braces scored better for alignment and marginal ridges (Table 3). There were almost no differences between the two groups for interproximal contacts. Again, none of these differences were statistically significant. The overall OGS scores of the Invisalign and braces groups at the 6-month recall were 12.5 (IQR: 9.25) and 14.5 (IQR: 12.5) for, respectively, a difference that was not statistically significant ($P = .367$).

Between T1 and T2, braces patients showed improvements in buccolingual inclination, occlusal contacts, and occlusal relationships, but only the alignment and buccolingual inclination changes were statistically significant (Table 4). Braces patients exhibited minimal changes for marginal ridges, overjet, interproximal contacts, and root angulation. The alignment and overjet of the aligner patients worsened significantly, but their buccolingual inclinations and occlusal relations improved. The marginal ridges, buccolingual inclination, occlusal contacts, overjet, interproximal contacts, and root angulation of the aligner patients changed minimally. None of the OGS component scores showed statistically significant between-group posttreatment differences. Between the end of treatment (T1) and the 6-month recall visit (T2), total OGS scores did not change for the aligner group and decreased for the braces group, but the difference was not statistically significant.

DISCUSSION

Braces patients in the present study finished 4.8 months earlier than the aligner patients. Invisalign patients have previously been reported to finish 3.6-5.5[3,16,19] months faster than braces patients. The longer treatment times with aligners in the present study could have been related to the 2-week intervals between trays, compliance, and refinements. All of the patients started treatment with Class I molars and canines, minimal crowding, no major overjet, and no open bites, which negated the need for anteroposterior and vertical corrections. This minimized patient compliance among the braces patients because they did not have to wear elastics. In contrast, the aligner patients had to wear their appliances, making their lack of compliance a greater likelihood and extending the treatment times of

Table 3. Medians and Interquartile Ranges (IQR) of OGS Scores at the 6-Month Recall (T2)

	Aligner Group		Braces Group		Difference
OGS Component and Overall Scores	Median (50%)	IQR (25%; 75%)	Median (50%)	IQR (25%; 75%)	*P* Value
Alignment	3.5	2.0; 5.5	3.0	2.0; 5.75	.993
Marginal ridges	1.5	0.0; 2.0	1.0	0.0; 2.0	.474
Buccolingual inclination	1.0	0.0; 2.25	2.0	0.0; 2.0	.586
Occlusal contacts	0.0	0.0; 2.25	1.0	0.0; 2.0	.373
Overjet	2.0	1.0; 5.25	3.0	1.0; 4.75	.740
Interproximal contacts	0.0	0.0; 0.0	0.0	0.0; 0.0	.209
Root angulation	0.0	0.0; 1.0	0.50	0.0; 2.0	.050
Occlusal relations	1.5	0.0; 4.0	2.5	0.25; 5.0	.289
OGS	12.5	8.0; 17.25	14.5	9.25; 21.75	.367

[a] OGS indictes objective grading system.

Table 4. Medians and Interquartile Ranges (IQR) of OGS Score Changes Between End of Treatment (T1) and the 6-Month Recall (T2)[a,*,**]

OGS Component and Overall Scores	Aligner Group		Braces Group		Difference
	Median (50%)	IQR (25%; 75%)	Median (50%)	IQR (25%; 75%)	*P* Value
Alignment	1.0**	0.0; 2.0	0.0*	0.0; 1.0	.307
Marginal ridges	0.0	−1.0; 0.0	0.0	−1.0; 0.0	.897
Buccolingual inclinations	0.0*	−1.25; 0.0	−1.0*	−2.75; 0.0	.274
Occlusal contacts	0.0	−2.0; 0.0	−1.0	−2.0; 0.0	.823
Overjet	0.0*	0.0; 1.0	0.0	0.0; 1.0	.551
Interproximal contacts	0.0	0.0; 0.0	0.0	0.0; 0.0	.113
Root angulation	0.0	0.0; 0.0	0.0	0.0; 0.0	.000
Occlusal relations	−1.0*	−2.0; 0.25	−0.50	−1.75; 0.0	.578
OGS	0	−4.5; 2.0	−1.5	−5.75; 2.75	.677

Probability of within-group changes over time [*prob $<$.05;** prob $<$.01].
[a] OGS indicates objective grading system.

at least some individuals. In addition, previous aligner studies did not specify whether there were refinements. The Invisalign patients in the present study had 1-2 refinements, which could have added weeks to months onto treatment duration.

The initial case difficulty cannot explain the difference in treatment times. Each point increase of the DI is thought to increase treatment duration by 11 days.[23] However, the braces patients in the present study started treatment with significantly higher DI scores (7.0) than the aligner patients (4.5) and, yet, they finished 4.8 months faster without the adjustment, and more than 7 months faster after the adjustment. It is important to emphasize that, even though the between-group difference in the DI was statistically significant, it was small. Based on ABO discrepancy index guidelines, a DI score of 7-15 is considered mild, 16-24 is moderate, and scores $\geq$25 are considered to be severe.[3]

At the end of treatment, the present study showed no significant between-group differences in the total OGS score, or for any of the component scores. Kuncio et al. also found no differences between braces and aligners in OGS scores or component scores.[20] In contrast, braces patients have been shown to end treatment with significantly better posttreatment buccolingual inclination, occlusal contacts, occlusal relationships, overjet, and total OGS scores than aligner patients.[3] The difference between this and the present study could be that, due to initial case complexity, their starting DI scores were 14.1 and 12.9 points higher than the aligner and braces patients in the present study, respectively. It is also possible that the different outcomes were due to the newer materials and technologies used to treat the Invisalign patients in the present study.

The present study also showed that there were no between-group differences 6 months post-retention. Kuncio et al. also found no statistically significant between-group differences in OGS scores 3 years after appliance removal.[20] Both their study and the present study showed no significant changes in the total OGS score, with a limited number of significant changes in the component scores, between the end of treatment and post-retention. This indicates that the components of occlusion that improved were offset by other components that worsened over time, essentially negating any changes of the total OGS score.

Both groups in the present study showed worsening of alignment and overjet from T1-T2, and improvements in buccolingual inclination and occlusal relationships. Aligner and braces patients followed 3 years posttreatment showed more pronounced worsening of alignment than the present study and no change in buccolingual inclination.[20] The smaller changes observed in the present study could have been due to the duration of the posttreatment period or to the low initial DI score for aligner patients. Nett et al., who evaluated 100 randomly chosen patients not treated with aligners, also reported significant worsening of alignment and improvement of buccolingual inclinations after a minimum of 10 years post-retention.[24] Together, these findings suggest that the posttreatment changes observed for the aligner cases were not treatment-related.

The cases in the present study had excellent treatment results. The overall and component OGS scores were much lower than those previously reported after treatment and post retention. For example, Djeu et al. had average total OGS scores of 45.4 and 32.2 for aligners and braces patients, respectively.[3] Kuncio et al. had average total OGS scores of 39.5 and 43.0 for aligner and braces patients, respectively.[20] The present study had median total OGS scores of 12.0 and 17.0 for aligner and braces patients, respectively. The present study also found much lower component scores than previously reported in the literature, partially reflecting the fact that the cases were initially simpler.

CONCLUSIONS

- Invisalign patients with simple Class I malocclusions, treated with SmartForce features and attachments, require 4.8 months longer treatment times than patients with simple malocclusions treated with traditional braces.
- For simple Class I malocclusions, aligners produce the same excellent occlusal results as traditional braces at the end of treatment.
- For simple Class I malocclusions, there are no differences in occlusal results between aligners and braces 6 months posttreatment.

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